

Kindly add the following claims:

C gp160 and [a] proteosome

? what is the

--5. The construct according to claim 1 wherein the gp160 and proteosome are present in a ratio between about 1:1 and 1:20.

B3 Sub E27 6. The construct according to claim 2 wherein the ratio range is between about 1:1 and 1:3.

Sub E27 7. The construct according to claim 2 wherein the ratio range is about 1:1.

Sub E3 8. A method for inducing antibody formation in a host comprising administering an effective amount of the construct of claim 1 or the composition of claim 2 to a host to induce the formation of an antibody that binds gp160.

9. The method according to claim 8 wherein the administration step involves multiple immunizations of the host.--

### REMARKS

Reconsideration is respectfully requested in light of the foregoing amendments and following remarks.

Claims 1-9 are pending. Claims 1, 3 and 4 have been amended to improve readability. Claim 2 has been amended to delete reference to "vaccine." Newly added dependent claims 5-9 are directed to embodiments not previously claimed. Support is to be found on page 30, at lines 21-23 (ratios), and page 37 through line 18 on page 40 (1:1 ratio and method of use).

The specification, as requested, has been amended to completely identify the parent applications and their status along with their relationship to the instant application. Priority under 35 USC 120 is requested.

A signed Rule 67 declaration will be submitted upon receipt by the undersigned.

The specification has been amended and the requisite sequence information in computer-readable form included to address the formal requirement noted by the Examiner.

A suitable specification will be submitted upon an indication of allowable subject matter.

The application has been amended to include an Abstract as requested.

With regard to the Examiner's comments regarding an Information Disclosure Statement, one was filed on or about October 2, 1998.

#### **Rejections under 35 USC 112, First Paragraph**

Claims 1-4 are rejected under 35 USC 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention. Applicant respectfully traverses.

The Examiner is evidently of the opinion that the specification does not provide sufficient detail and evidence to permit practice of the invention in the context of an AIDS "vaccine", which is sufficient to provide protection against any of the AIDS viruses. The Examiner does not appear to question the inducement of antibodies in response to the inoculation with the claimed composition or construct.

It should be noted that claim 1 is merely drawn to a construct comprising gp160 and proteosome and that dependent claims 2-4 recite the "vaccine" limitation. The Examiner's comments are more applicable to these dependent claims and not the gp160 construct *per se*.

The ability of the gp160 construct to elicit antibody production is clearly shown in Table 6 on page 40 of the specification. The preparation of the gp160 construct-containing composition is clearly shown starting on page 37 at line 20.

With regard to the use of the novel composition as a preventative vaccine, applicant relies on conventional vaccine technologies and routine experimentation for enablement. The Examiner questions this reliance in light of the cited references.

To advance prosecution, dependent claim 2 has been amended to delete reference to "vaccine" and to add "inducing" antibody production.

In light of the amendment to the claims and the remarks, *supra*, withdrawal of the rejection is respectfully requested.

### **Rejections under 35 USC 103**

Claims 1-4 are rejected under 35 USC 103 as being unpatentable over Lowell *et al.* (U) or Lowell *et al.* (V) or Smith *et al.* (W) or Avraham *et al.* (X) in view of Ratner *et al.* (Y).

Applicant respectfully traverses.

Applicant submits that the rejection as framed employs an obvious-to-try rationale. As noted by the Examiner, the primary references do not teach gp160 but merely teach the use of proteosomes in a vaccine context. Ratner is cited for its teaching of the existence of gp160. The Examiner states that Ratner *et al.* teach the complete genome of HIV (HTLV-III) including the sequence of gp160.

The Examiner then proposes that since envelope proteins of viruses are antigenic, it would have been obvious to first isolate and purify gp160 and then employ it as the "antigenic" protein/polypeptide in the process and compositions taught by the primary references.

It is submitted that there is a high degree of unpredictability in the vaccine, immunology arts. (The Examiner evidently concurs. Note the preceding rejection based on the first paragraph of section 112.) In light of this, it is submitted that the record relied upon by the Examiner does not establish an expected likelihood of success. The cited Avraham *et al.*, on its face, does not. It is directed to V3 peptides and not gp160. It is not apparent from the record why V3 peptides would be expected to be chemically and immunologically equivalent to the gp160 protein. Further, it is not clear why the degree of success achieved by the claimed invention, which is reflected in Table 6, on page 70, would be expected.

In light of this, it is submitted that a proper *prima facie* case has not been established and the rejection withdrawn. This is respectfully requested.

Further, it is noted that all the primary references were published after the date of the earliest parent application, U.S. Serial No. 07/065,440, filed June 23, 1997. (The use of proteosome-protein complexes is disclosed in the context of a vaccine for AIDS and other HTLV-related diseases. See section bridging pages 22 and 23 of the parent specification.) Further, it is noted that applicant is listed as a co-author on each of the primary references.

### **Conclusion**


Having addressed all the rejections and objections, allowance of the application is believed to be in order. A notice to this effect is respectfully requested.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 21-0380** referencing docket no. 378332000110. However, the Assistant Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

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